K 050143

FEB - 1 2005

510(k) Summary

Date: November 29, 2004

This summary of 510(k)-safety and effectiveness information is for the *OmniPro*™ System.

1. **Company making the submission:**

Company Name:	**Mays and Associates, Inc.**
Address:	**315 Springhouse Circle**
	Franklin, TN 37067
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	(615) 794-9792 Fax
Contact:	**Burke Mays**
	President
E-mail:	**bmays4@bellsouth.net**

2. **Submission correspondent:**

Company Name:	Delphi Consulting Group
Address:	11874 South Evelyn Circle
	Houston, Texas 77071-3404
Telephone:	832-285-9423 Voice
	832-615-3550 Fax
Contact:	J. Harvey Knauss
	Consultant
E-mail:	harvey@delphiconsulting.com

3. **Predicate Device:**

   Compumedics E-Series EEG System, K000068, Compumedics Neuro Science Pty LTD, Minneapolis, MN 55432 and Cadwell Easy II System K946094, Cadwell Laboratories, Inc., Kennewick, WA 99336.

4. **Classifications Names & Citations**:

   Electroencephalograph, Class II, 882.1400, GWQ, Neurology

5. **Trade Name:**

   OmniPro™ System

6. **Description:**

   The OmniAmp is a dual-purpose amplifier system for use in polysomnogram (PSG) and electroencephalogram (EEG) studies in a hospital or diagnostic center.

The system hardware consists of an amplifier module with electrode inputs, an interface module and a personal computer (PC) with a data acquisition (DAQ) board. Electrodes

and sensors on the patient are connected to the amplifier module, which in turn is connected via a multiconductor cable to an interface box. The interface box is connected via a second multiconductor cable to the DAQ board in the PC, which is used to process display and store the EEG or PSG data. DC power to the amplifier is supplied from the DAQ board through the multiconductor cable. The PC at the patient location is connected to a second PC at a remote monitoring center via modem over the public switched telephone network (PSTN). In EEG studies, the remote PC is used to monitor the waveform data as it is collected by the patient PC to ensure adequate electrode placement and signal quality. At the end of the study, the recorded data is transferred from the patient PC to the remote PC, where it is analyzed and stored.

The amplifier module comes in PSG and EEG versions. These modules utilize the same internal amplifier hardware. They differ in terms of the configuration of the electrode inputs to the amplifier channels. Both versions of the amplifier modules have male safety electrode receptacles for connection of each electrode. They have a graphic panel to indicate the location and name for each electrode connection. The PSG amplifier module has an OEM oximetry module that works with a finger sensor to detect the oxygen saturation (SPO2) and pulse rate. Both versions utilize the same interface cable to connect the amplifier module to an interface module located next to the PC. The interface cable may be up to 50 feet long and is shielded to reduce EMI. Both versions may have a clip to secure the box to the bed covers and may have a means to connect a lanyard for hanging the module from the patient's neck to allow for patient mobility.

The amplifier module has twenty-five electrically isolated differential amplifier channels. Twenty-one of the amplifier channels has the same gain and bandwidth settings and is used for the EEG, EMG, and EOG signals. The amplifier has one channel set for ECG, two channels set for interface with the respiratory effort piezoelectric belt sensors and one channel set to interface with the nasal airflow thermal type sensors. In the PSG mode, the electrode box connects thirteen (twelve in home use configuration) EEG/EMG/EOG amplifier channels, one ECG channel and the three respiratory amplifier channels to patient electrodes. In the EEG mode, the electrode box connects twenty-one amplifiers, set for EEG signals, and one ECG amplifier to the appropriate patient electrodes. The output cable connects all twenty-five-amplifier channels to the DAQ board where the system selects the channels for use in the patient study.

The interface cable carries status information between the interface module and the amplifier module in addition to the measured signals and power In the EEG mode, a jumper in the electrode cap receptacle indicates when it is connected. A digital line from the DAQ card activates the calibration signal to the amplifier channels. These digital inputs and outputs are connected from the amplifier to the DAQ board in the PC via the interface cable. If necessary, the Digital Input/Output (DIO) lines from the DAQ board in the PC will be used to select between PSG and EEG modes and to select the gain of the amplifier channels. The cable from the amplifier module to the PC DAQ board can be up to 50 feet long. It is shielded and has wires grouped to separate sensitive signal wires from the oximeter serial data, any DIO lines and +5V power for the amplifier

7. **Indications for Use:**

The *OmniPro*™ System is intended for the measuring, recording and analysis of the electrical activity of a patient's brain through the attachment of multiple electrodes at various locations to aid in monitoring and diagnosis as routinely found in clinical

setting for EEG/EMG/EOG/ECG/Air Flow/Oximetry.

8. **Contra-indications:**

No absolute contra-indications known.

9. **Technological characteristics, Comparison to predicate device:**

Comparison of OmniAmp and Compumedics EEG/PSG Systems K000068, and Cadwell Easy II System K946094

Characteristic	**Mays and Assoc. *OmniPro*™ This Submission**	**Compumedics E-Series EEG/PSG K000068**	**Cadwell Easy II K946094**
Configuration	Mobile Cart or Desktop	Mobile Cart or Desktop	Mobile Cart or Desktop
Headbox/preamp configuration	25 Ch Isolated Amplifier with Analog Output	32 Ch Isolated Amplifier with Digital Output	32 Ch Isolated Amplifier and 7 active reference pairs
Number of Channels	32 Recordable/displayed	32 Recordable/displayed/isolated	32
Montage Selection	Up to 1000 Programmable	256 Programmable	Virtually unlimited
Sensitivity Controls	Yes	Yes	Yes
Fixed Low Frequency Analog Filters	Yes	Yes	Yes
Fixed High Frequency Analog Filters	Yes	Yes	Yes
Selectable Digital High and Low Frequency Filters	Yes	Yes	Yes
Master Notch Filter	Yes, Master Off, Enabled per Channel	Yes	Yes
Sample Rate	Up to1080 Hz per channel	Up to 512 Hz per channel	2400 Hz/channel
Noise	2 uVpp	2 uVpp	3 uVpp
Electrode Impedance Check	LED indicators on Amplifier Module	LED indicators on Amplifier Module	LED indicators on Amplifier Module
Calibration Check	100 uVpp square wave injected at amplifier module	100 uVpp square wave injected at headbox	Square wave, 50 mV, 0.5 Hz
System Types	Laboratory Based or Portable	Laboratory Based or Portable	LED indicators on Amplifier Module
Time Base Controls	Yes	Yes	Yes

Selectable Montage Sequences	Yes	Yes	Yes
Automatic Event Logging	Yes	Yes	Yes
Annotations On Study	Yes	Yes	Yes
Timers on Study Events	Yes	Yes	Yes
Storage	Hard Disk, Writable CD, USB Flash	Hard disk, Writable CD, optical disk	Hard disk, Writable CD, optical disk
Study Modes	Routine EEG Recording, Routine PSG Recording, Retrieval and Replay	Routine EEG Recording, Long Term Monitoring, Retrieval and Replay	Routine EEG Recording, Long Term Monitoring, Retrieval and Replay
EEG/PSG	Yes ✓	Yes ✓	Yes

10. **Review of Performance Testing:**

The following is an overview of tests that have been conducted successfully for the *OmniPro*™ System:

- Safety Tests to conform to IEC 60601-1, IEC60601-2-16 to ensure that there is no potential for detrimental effects on patients, other persons, or the surroundings.
- Electromagnetic Compatibility tests to IEC 60601-1-2 to ensure no intolerable magnetic disturbances are introduced into its electromagnetic environment.
- Immunity tests to IEC 60601-1-2 to ensure that the EEG equipment has the ability to operate satisfactorily in its electromagnetic environment.
- Compliance testing to Software Test Specification to ensure that the system conforms to all of the system design requirements.

11. Conclusion:

Based on extensive performance testing and a comparison to the predicate device, it is the conclusion of Mays and Associates, Inc., that the OmniPro™ System is substantially equivalent to devices already on the market (cleared by the 510(k) process) and presents no new concerns regarding safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB - 1 2005

Mays and Associates, Inc.
c/o Mr. Ned E. Devine, Jr.
Entela, Inc.
3033 Madison Avenue, SE
Grand Rapids, Michigan 49548

Re: K050143
Trade/Device Name: OmniPro™ System
Regulation Number: 21 CFR 882.1400
Regulation Name: Electroencephalograph
Regulatory Class: II
Product Code: GWQ
Dated: January 21, 2005
Received: January 21, 2005

Dear Mr. Devine:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for Mark N. Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

510(k) Number K 050143

Device Name: *OmniPro*™ System

Indications for Use:

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Prescription Use (YES) (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Melkerson

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K050143